K110886

JUN 30 2011

510(k) Summary

As Required by 21 CFR Section 807.92 (c)

1. *Submitter Information*

Name:	SOTA Imaging
Address:	1073 North Batavia Street Suite B
	Orange, CA 92867 USA
Telephone Number:	(714) 532-6100
Fax Number:	(714) 532-6107
Contact Person:	Brian Kim, President
Date Prepared:	March 23, 2011

2. *Identification of the Device*

Trade Name:	CLIO/CLIOSOFT
Common/Usual Name:	Dental Image Management System
Classification Name:	Picture Archiving and Communications System or
	System, X-ray, Extraroal Source, Digital
Product Code:	LLZ or MUH
Regulation:	21 CFR 892.2050 or 21 CFR 892.1800, Class II

3. *Equivalent legally Marketed Device*

Manufacturer:	GENDEX DENTAL SYSTEMS
Product Name:	VixWin Pro
Product Code:	MUH and LLZ
Regulation:	21 CFR 892.1800 and 21 CFR 892.2050, Class II
510(k) Number:	K060178

Manufacturer:	TOSHIBA AMERICA ELECTRONIC COMPONENTS, INC.
Product Name:	Digital X-ray Sensor
Product Code:	MUH
Regulation:	21 CFR 892.1800, Class II
510(k) Number:	K092537

4. *Device Description*

CLIO/CLIOSOFT is a system for general dental diagnostic imaging. CLIO is an intraoral x-ray sensor and CLIOSOFT is a software program. CLIO has size 1 and size 2 sensors. CLIO sensor connects to the PC-compatible computer via an USB port. CLIOSOFT controls capture, display, treatment, review, store, print, and distribute digital x-ray images from CLIO sensors. It can also handle other types of images acquired by digitizing film with a flatbed scanner, or color images from an intraoral or extraoral dental camera such as the Claris i310 series. CLIO/CLIOSOFT runs on standard PC-compatible computers.

CLIO connects to the computer via USB port.

When properly installed in your computer, CLIOSOFT lets you:

- Control the direct capture of digital x-ray images from the intraoral sensor CLIO.
- View and capture live image from intraoral cameras via USB 2.0 or video capture card.
- Import images from various sources such as radiographic devices, flatbed scanner, digital camera, and generic image devices.
- Export, e-mail, and print images.
- Process digital images with several tools to enhance their diagnostic value.
- Create a database of patients and store images in patient folders.

5. *Indications for Use*

CLIOSOFT is indicated for use as a clinical software application that receives images and data from CLIO sensor and various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). In addition, CLIOSOFT enables the storage of clinical notes and clinical exam data.

It is intended to acquire, display, process, edit (e.g., resize, adjust contrast, annotate, etc.), review, store, print, and distribute images using standard PC hardware.

6. *Safety and Effectiveness, Comparison to Predicate Device*

CLIO/CLIOSOFT is safe and effective as the predicate device cited above.

6.1 Substantial Equivalence Chart

Description	VixWin Pro (K060178)	Toshiba Digital X-ray Sensor (K092537)	CLIO/CLIOSOFT
Indications for use	Controls capture, display, treatment, analysis and saving of X-ray digital images from DenOptix®, Visualix®/GX-S, Orthoralix 9200 DPI and DDE digital imaging systems produced by Gendex. It can also handle other types of digital images, e.g. color images from an intraoral or extraoral dental camera, such as the Gendex Concept IV series, or images acquired by digitizing film with a flat bed scanner.	Toshiba Digital X-ray Sensor is an intraoral receiver of X-ray energy by the dentist to obtain instant images of teeth and the oral cavity of patients. Images are transmitted to a computer for display.	CLIOSOFT is indicated for use as a clinical software application that receives images and data from CLIO sensor and various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). In addition, CLIOSOFT enables the storage of clinical notes and clinical exam data. It is intended to acquire, display, process, edit (e.g., resize, adjust contrast, annotate, etc), review, store, print, and distribute images using standard PC hardware.
Implementation	Software only	Sensor only	Sensor and/or Software
Number of sensors	-	4 two for size 1 and two for size 2	2 Size 1 and size 2
Sensor size (mm)	-	Size 1: 40.1 x 25.1 Size 2 soft: 44.4 x 32.6 Size 2 hard: 43.7 x 31.9	Size 1: 36.73 x 24.35 Size 2: 42.80 x 30.49
Technology	-	CMOS	CMOS
Interface to PC	-	USB	USB
Dynamic Range	-	4096:1	4096:1
Sensor cable length (m)	-	2.5	3
Host platform	PC	-	PC
Operating system	Windows 98, 2000, XP	-	Windows XP, Vista, 7 (32/64 bit)
Host RAM	32 MB	-	512 MB
Host Magnetic Storage	4 GB, 9 GB or higher recommended	-	80 GB, 250 GB or higher recommended
CD-ROM	Yes	-	Yes
Host Processor	Intel Pentium 133 MHz, 200 MHz or higher recommended	-	Intel Pentium 4 2.0 GHz or higher
Host Monitor Size	SVGA, XGA recommended	-	XGA, SXGA recommended
Display Resolution	800x600, 1024x768 recommended	-	1024x768, 1280x1024 recommended

6.2 Meaningful Differences

The sensor included in the CLIO/CLIOSOFT system is provided as OEM and the specification and configuration is similar to TOSHIBA Digital X-ray Sensor (K092537) that already approved. The sensor is safe and effective based on the following references:

- CB TEST CERTIFICATE for IEC 60601-1:1988 +A1:1991 +A2:1995 and
  CB TEST CERTIFICATE for IEC 60601-1:2005 (except 60601-1-6)
  see Appendix C

- SAFETY TEST ACCORDING TO THE STANDARD IEC 60601-1:1988 +A1:1991 +A2:1995
  see Appendix D

- SAFETY TEST ACCORDING TO THE STANDARD IEC 60601-1:2005 (without 60601-1-6)
  see Appendix E

- EMC TEST ACCORDING TO THE STANDARD EN 60601-1-2:2007
  see Annex Document No. 4 in Appendix D

- EMC TEST ACCORDING TO THE STANDARD EN 60601-1-2:2007
  see Attachment No. 9 in Appendix E

- Software Validation
  see Exhibit 14

- Reference 510(k) sensor: **K092537**

7. Conclusion

CLIO/CLIOSOFT is substantially equivalent to legally marketed Image Processing Systems (i.e. PACS).

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Bram Kim
President
SOTA Precision Optics, Inc. DBA SOTA Imaging
1073 North Batavia Street Suite B
ORANGE CA 92867

JUN 30 2011

Re: K110886
Trade/Device Name: CLIO/CLIOSOFT
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 9, 2011
Received: June 14, 2011

Dear Mr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K110886

Device Name: CLIO/CLIOSOFT

Indications for Use:

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It is intended to acquire, display, edit (e.g., resize, adjust contrast, crop, etc.), review, store, print, and distribute images using standard PC hardware.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pickl

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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